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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,995	07/28/2003	Tatsuo Kaneko	26L-001	4262

23400 7590 04/05/2005

POSZ LAW GROUP, PLC
12040 SOUTH LAKES DRIVE
SUITE 101
RESTON, VA 20191

EXAMINER

WU, SHEAN CHIU

ART UNIT	PAPER NUMBER
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1756

DATE MAILED: 04/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/627,995

Applicant(s)

KANEKO ET AL.

Examiner

Shean C. Wu

Art Unit

1756

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 11-17 is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 9/16/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

1. Claims 1-3 and 5-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim language "tissue-derived compound or the derivatives" is vague because the "tissue-derived compound" and "derivatives" are not clearly defined. What is the difference between these two terms?

The claim language "aromatic series natural product" in Claims 5-6 and 8 is not defined.

Regarding claims 7 and 10, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

2. Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the species-a bio-liquid crystal polymer comprising a 4HCA and LCA, does not reasonably provide enablement for other species other than the species exemplified in the specification. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. There are no exact compounds taught in the specification. There are only disclosed the tissue-derived compound having reactive groups described from page 11, line 23 to page 12, line 4. Also, the claim language "aromatic series natural products" is broadly claimed. What are these natural products with aromatic series?

Art Unit: 1756

The claims are broader than the enabling disclosure. The claimed invention is not supported by examples commensurate in scope. There are no teachings how one of the ordinary skill in the art can synthesize the bio-liquid crystal polymer except the one exemplified in the specification. The claimed polymer containing the groups shown on pages 11 and 12 has enormous permutations. No properties are general specified for most of compounds. Without knowledge of the properties of species commensurate in scope with the claims, Applicants invite the skilled artisan to first synthesize and then test the species before a use can be undue. The properties of LC vary greatly with the number and type of rings, bonding, lateral and terminal substituents and polarities. All govern the properties of the LC and mixture thereof, which further determine the utility in one of a multitude of functionally distinct compositions and applications. Applicants claim offer little more than an invitation to experiment or even presupposing the species call can be readily made.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3 and 5-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Stupp et al. (US 5,932,539).

The reference discloses new biodegradable polymers comprise a lipophilic molecule (can derived form fatty acid) linked to a polyionic poly (amino acid) or

polyionic polysaccharide through a divalent linker comprising a natural metabolite or a polymer biodegradable into natural metabolites. The reference polymers contain a lipophilic molecule with affinity for cell membranes and a polyionic molecule with affinity for extracellular matrix. They have self-assembly properties characteristic of liquid crystals. The polymers can be used alone or as a component of an implant matrix composition, e.g. containing viable cells such as chondrocytes or growth factors, enzymes, hormones, nucleic acids or drugs, for tissue treatment and/or repair or for controlled release of active agents. Also, see the abstract.

The reference further discloses that the reference polymer exhibits pre-determined temperature (col. 1, lines 60-65). The polyesters of the reference are disclosed on page 2, lines 13-22, which are prepared by the polymerization of one or more cyclic esters of hydroxyl acids. The polyester of the reference comprises a homopolymer, copolymer or terpolymer of hydroxyl acids. (col. 3, lines 1-41). See Synthesis II-IV. The reference anticipates the claimed invention.

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. It is noted that the references submitted with IDS filed 9/16/4 should be cited the original source, which the first one is cited from Journal of Applied Polymer Science (2001), 82(10), pages 2357-2364 and the second reference submitted herewith Japanese by Yoshiharu is not known. Applicants should provide complete information in PTO-892 form. If Applicants wish second reference to be considered by the Examiner they should provide English translation.


Art Unit: 1756

6. Claims 11-17 are allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shean C. Wu whose telephone number is 571-272-1393. The examiner can normally be reached on 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Huff can be reached on 571-272-1385. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Shean C Wu
Primary Examiner
Art Unit 1756

SCW